AMENDMENTS TO THE DRAWINGS

Figures 1-4 have been labeled "PRIOR ART".

Attachment: 4 Replacement Sheets

REMARKS

Dealing with preliminary matters first, Applicants thank the Examiner for acknowledging Applicants' claim to priority and receipt of the priority document in the national stage application. Further, it is noted with appreciation that the Examiner has considered the references cited in the Information Disclosure Statements filed March 21 and December 5, 2005, respectively.

The Examiner has objected to the specification and drawings. In order to overcome the Examiner's objections, Applicants have amended the specification and drawings as requested by the Examiner.

Claims 1 and 4-7 are all the claims pending in the application and have been rejected under 35 U.S.C. § 112 (second paragraph) as being indefinite. It is submitted that the above amendments to the claims overcomes this rejection.

Claims 1 and 4-7 are rejected under 35 U.S.C. § 102(a) as being anticipated by JP 2003-83958). Still further, claims 1 and 4-7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kikuchi, et al. (JP 2001-258868) in view of Boyd, et al. (U.S. Patent No. 5,919,711).

In order to clarify differences from the applied references, particularly Boyd et al., Applicants have amended claims 1 and 6 to recite that a blood cell fraction container (501) is disposed midway in the flow channel (303). Original claims 1 and 6 recite that the plasma separating means 104 is disposed midway in the flow channel, but did not clearly refer that the claimed blood cell fraction container (501), which is a part of the plasma separating means, is disposed midway in the flow channel (303). Thus, the claims have been amended to positively

recite this feature. Antecedent basis for these amendments are seen in Figs. 5, 6, 8, 9, 10, 11, 12; page 15, lines 8 11; and page 27, lines 23 24.

Priority Documents:

In order to traverse the Prior Art Rejection based on the reference JP 2003-83958, Applicants submit a verified English translation of the priority document. It is noted that the priority date (9/20/2002) of the subject invention predates the publication date (3/19/03) of JP 2003-83958. Thus, this rejection should be withdrawn.

Present Invention:

In the present blood analysis apparatus, blood cells and plasma are centrifugally separated. Specifically, a part of a flow channel into which blood is introduced is formed as a U shaped flow channel. The lowermost portion of the U shaped flow channel is positioned in a centrifugal force pressurizing direction and is formed into a blood cell fraction container which collects blood cell fraction, so that the upstream and downstream sides of the flow channel communicate with each other in an upper space of the blood cell fraction container. To ensure the connection of the plasma fractions in the upstream and downstream portions of the flow channel, a capacity or volume of the blood cell fraction container positioned in the centrifugal force pressurizing direction from an upper inner wall of the lowermost portion of the U shaped flow channel is set to be larger than the amount of the blood cell fraction in the whole amount of blood introduced into the flow channel.

With such arrangement, the plasma fraction can continuously exist in both of the upstream and downstream portions of the flow channel without being divided by the blood cell fraction after the centrifugation. The plasma in a required amount can be fed into the analysis

means using a smaller amount of the whole blood, simply a half amount of a blood sample as compared with a conventional flow channel constitution such as Kikuchi et al. (JP 2001 258868). The whole blood can be utilized more efficiently, which is suitable for the shortening the flow channel and the reduction of the apparatus size. Furthermore, the amount of the blood to be collected is decreased, thereby reducing a burden on a subject from whom blood is to be collected.

Kikuchi et al. (JP 2001 258868):

The blood analysis apparatus of Kikuchi et al. is described in the background section of the present application.

As correctly pointed out by the Examiner, Kikuchi et al. fails to teach the plasma separating means located in the lowermost portion of the U-shaped flow channel includes a blood cell fraction container that allows plasma in both the upstream and downstream portions of the flow channel to remain in contact with one another in an upper space of the blood cell fraction container.

Clearly, the upstream and downstream portions of the flow channel of Kikuchi et al. are not constituted to communicate with each other.

Boyd et al. (USP 5,919,711):

In the Office Action, page 7, the Examiner states that, in Boyd et al., a substantially U-shaped flow channel extends between an inlet port and an outlet port, and a blood cell fraction container is located at the lowermost end of the U-shaped channel.

It should be noted that the flow channel of Boyd et al. is not formed as a U-shaped, but as a Y-shaped flow channel. Please refer the attached copies of Figs. 5 and 6 of Boyd et al. with hand-written indications for the Examiner's convenience.

In Boyd et al., an inlet passageway 52 is connected to the deposition well 38 in which the blood sample 36 is deposited (column 3, lines 64 66; column 4, lines 1 2 and 40 42; Figs. 4, 5). The inlet (i.e., upstream) passageway 52 is branched midway. The branched outlet passageway 56 extends upwardly to the entry (opening) 55 of the test well 54. Clearly, the outlet passageway 56 is just the downstream portion of the flow channel in the meaning of the present invention. The inlet (upstream) passageway 52 further extends downwards from the branching point and connects to the separation well (container) 48. The passageway 58 is not a downstream passageway but rather, an overflow passageway. The overflow passageway 58 is connected to the separation well 48 and extends upwardly therefrom to an overflow well segment 68 through a restriction 70.

Further, the overflow passageway 58 communicates with a vent passageway 60 and passageway 62, and these vent passageways 60, 62 are connected to vent opening 21 in top plate 14 (Fig. 1) to allow liquids to be transferred through the various passageways to the various wells without the build up of back pressure (column 4, lines 40 49; Figs, 4 5).

Through the overflow passageway 58, an excess amount of blood sample overflows into an overflow well 50. In other words, the blood sample introduced in the cartridge 10 of Boyd et al. is metered by the overflow passage 58 and the overflow well 50 (column 5, lines 5 6, 16 and 42).

The blood filled in the overflow passageway 58 is separated into the blood cell fraction and plasma fraction by the centrifugal process. However, separated plasma remaining in the overflow channel 58 cannot be transferred to the outlet port (the opening 55 of the test well 54).

Further, the outlet passageway 56 is not directly connected to the separation container (well) 38. The outlet passageway 56 is branched midway of the inlet passageway 52 (which is the upstream portion of the flow channel).

More specifically, the upstream portion of the flow channel is the portion of the inlet passageway 52 above the branching point, and the downstream portion of the flow channel (between the deposition well 38 and the opening 55) is the outlet passageway 56 branched off at the branching point. Please refer the attached copies of Figs. 5, 6 of Boyd et al.

It is true that the two passageways 56, 58 are constituted to communicate with each other in an upper space of the container 48 and the passageways 56, 58 approximately form a U shaped flow channel.

However, the upstream portion (i.e., the inlet passageway 52 above the branching point) and the downstream portion (i.e., the outlet passageway 56 above the branching point) are constituted to communicate with each other not in an upper space of the container 48, but rather at the branching point of the inlet passageway 52 (Figs. 4, 5).

Thus, the flow channel of Boyd et al. is not formed as a U shaped flow channel, but as a Y shaped flow channel. In Boyd et al., the upstream and downstream portions of the flow channel directly communicate each other at the branching point of the Y shaped flow channel. See the attached copy of Fig. 5 of Boyd et al.

In additions, Boyd et al. have no teaching such that a capacity of the container 48 is larger than the amount of the blood cell introduced into the whole [U shaped] Y shaped flow channel.

Note again that the overflow passageway 66 meters the amount of the whole blood introduced in the container 48 and three passageways 52, 56, 58 by the metering level defined by the restriction 70 (Figs. 5, 7). The excess amount of the whole blood is transferred to the overflow well 50 (Fig. 5).

Boyd et al. requires that a capacity of the container 48 be larger than the amount of the blood cell fraction in the whole blood introduced into the container 48 and three passageways 52, 56, 58 below the metering level. It is not necessary that the capacity of the container 48 is larger than the total amount of the blood cell fraction in the whole blood introduced from the inlet port (deposition well 38) into the flow channels.

As described above, in the art of Boyd et al., the blood cell fraction container 48 is not disposed midway in the flow channel connecting the blood inlet port (deposition well 38) and the blood outlet port (opening 55). Rather, the container 48 is disposed under the branching point of the inlet passageway 52, and therefore, the upstream portion (the inlet passageway 52 upper from the branched point) and the downstream portion (the outlet passageway 56) are brought in contact with each other at the branching point of the Y shaped flow channel, but not in the upper space of the container 48.

In contrast, with the claimed invention, the flow channel 303 connecting between the blood inlet port 302 and the blood outlet port(s) 304, 305 is formed as U shaped flow channel without using branching channels. And the lowermost portion of the U shaped flow channel constitutes the claimed blood cell fraction container 501. Thus, the blood cell fraction container

in the claimed invention is disposed midway the U shaped flow channel. Therefore the upstream and downstream portions 303a, 303b can be brought direct contact with each other in an upper space of the container 501.

Boyd et al. neither teach nor suggest such features of the present invention.

Furthermore, the present apparatus and method has great advantages over Boyd et al.

First, the whole blood sample can be efficiently utilized in the present invention. In the device of Boyd et al., the separated plasma remained in the overflow passageway 58 cannot be used for analysis. Although the whole blood introduced into the overflow well 50 is also separated into the blood cell fraction and plasma fraction by centrifugal process, the separated plasma remained in the overflow well 50 cannot be utilized for analysis.

In connection with this matter, the Examiner states in the Office Action, page 8, lines 9-10, that, in Boyd et al, more accurate result can be obtained by having the entire plasma portion of a blood sample at the analysis section. Applicants believe that the Examiner misinterpreted Boyd et al. In Boyd et al., the entire plasma portion of the blood sample cannot be used for analysis. The separated plasma remained in the overflow well 50 and in the flow channel portion below the branching point of the Y-shaped flow channel cannot be transferred to the outlet port 55.

In contrast, with the claimed invention, all of separated plasma is remained in the upstream and downstream portions of U shaped flow channel, and therefore all of separated plasma can be used for analysis.

Second, the art of Boyd et al. is not suitable for shortening of the flow channel and the reduction of the apparatus size. The apparatus of Boyd et al. must require additional vent lines communicating with the separation well 48. Boyd et al. use the overflow passageway 58 and

vent passageways 60, 62 as such vent lines (column 4, lines 40 57; Fig. 5). These vent lines cause the complexity of the flow channel arrangement, thereby the apparatus size is increased.

Compared with Boyd et al., the present invention has simple flow channel arrangement without using any vent lines. This realizes the shortening of the flow and the reduction of the apparatus size.

The present invention is fully distinguishable over Boyd et al. and patentable thereover.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Brian W. Hannon/

Brian W. Hannon
Registration No. 32,778

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

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Boyd. et al D2

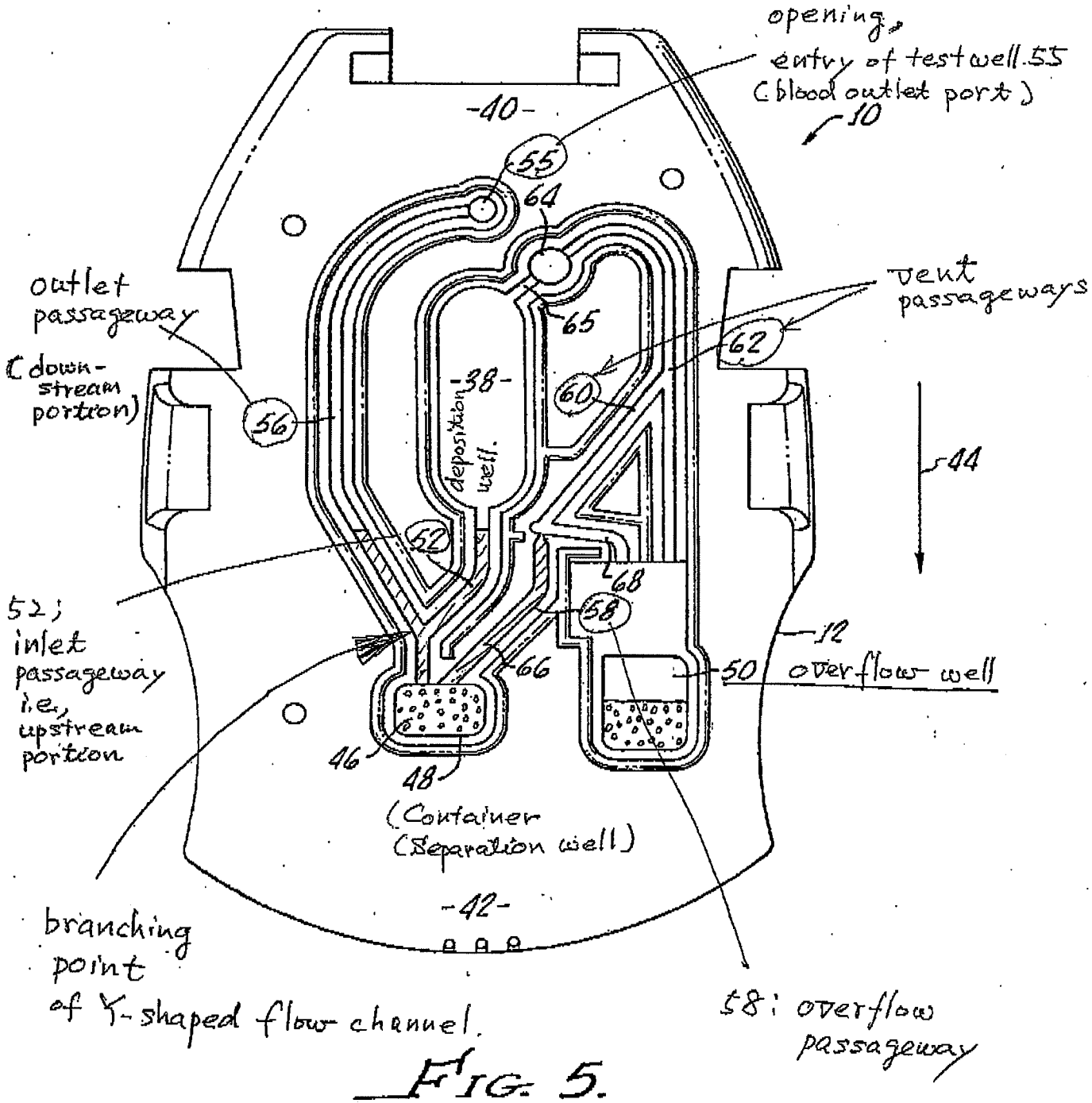
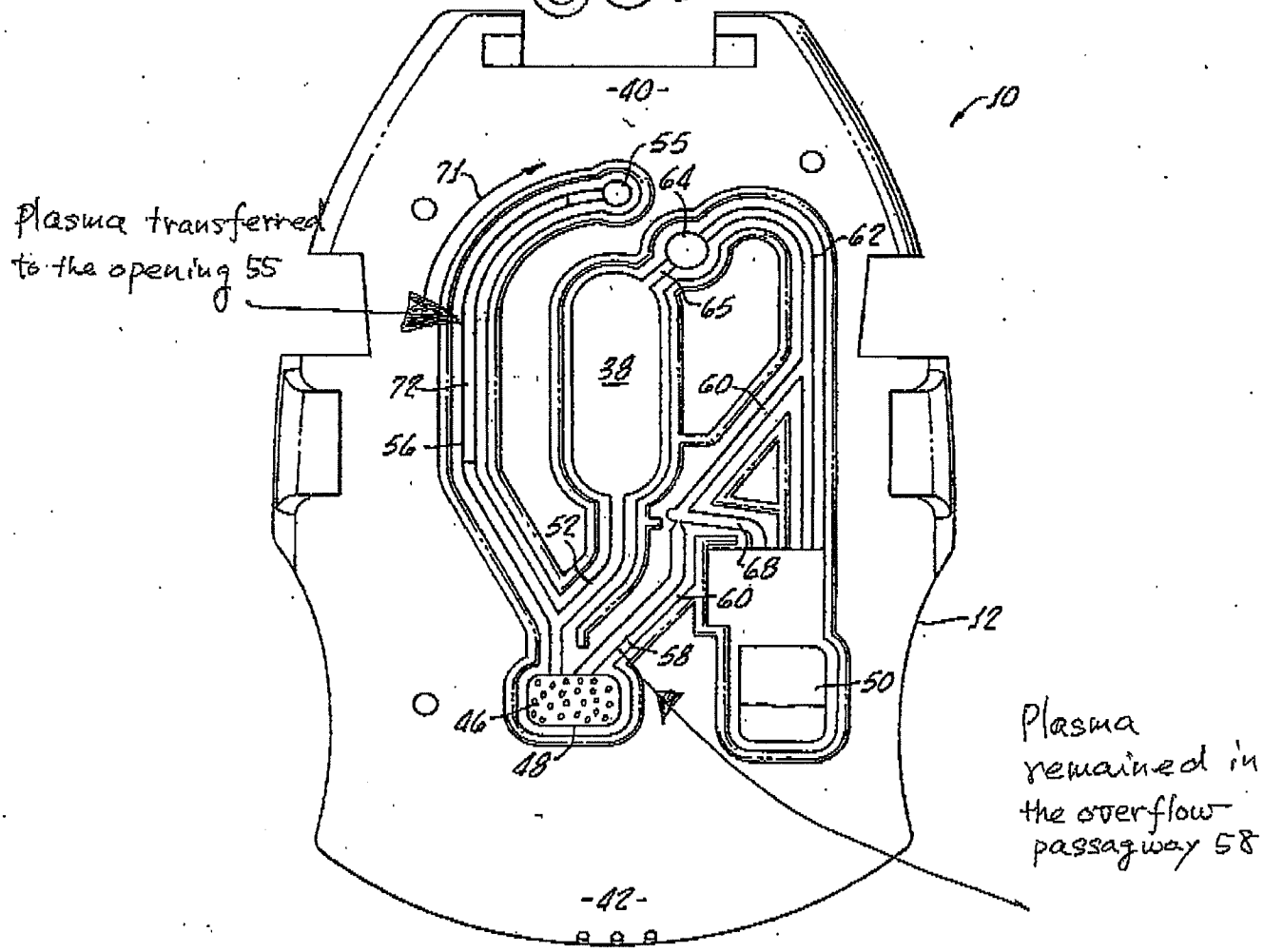


FIG. 5.

Boyd et al D2

U.S. Patent Jul. 6, 1999 Sheet 5 of 5 5,919,711

FIG. 6.



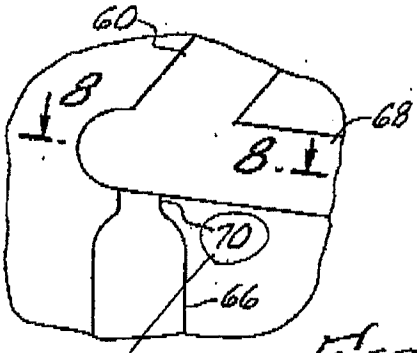


FIG. 7.

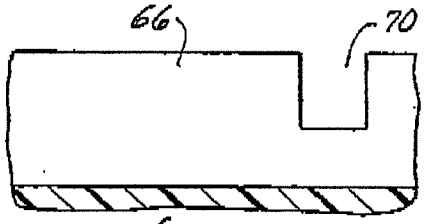


FIG. 8.

Restriction defining the metering level.